

## Osborne, Kevin (PMMC Legal)

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**From:** Carchman, Loreen  
**Sent:** Monday, August 20, 2001 11:33 AM  
**To:** Osborne, Kevin (PMMC Legal)  
**Cc:** Venable, Bristow; Oey, Jan  
**Subject:** RE: Contract Language for Main TES

Here is the tentative timeline. If it gets revised by Covance, I will let you know.

-L



Key milestones for  
Main TES.do...

-----Original Message-----

**From:** Osborne, Kevin (PMMC Legal)  
**Sent:** Friday, August 17, 2001 5:00 PM  
**To:** Carchman, Loreen  
**Cc:** Venable, Bristow; Oey, Jan  
**Subject:** RE: Contract Language for Main TES

As w/ other agmts., I suggest a full timeline be developed so this date can be met. When can this be done?

-----Original Message-----

**From:** Carchman, Loreen  
**Sent:** Friday, August 17, 2001 9:15 AM  
**To:** Osborne, Kevin (PMMC Legal)  
**Cc:** Venable, Bristow; Oey, Jan  
**Subject:** RE: Contract Language for Main TES

We would like to have this first contract signed by 10/01/01. Covance is in the process of putting together a scope of work and budget. Once this is received, we can move forward on this first draft.

-L

-----Original Message-----

**From:** Osborne, Kevin (PMMC Legal)  
**Sent:** Thursday, August 02, 2001 11:14 AM  
**To:** Carchman, Loreen  
**Cc:** Oey, Jan; Venable, Bristow  
**Subject:** RE: Contract Language for Main TES

Loreen-

I suggest we arrange a meeting w/ John R. et al. to discuss. Also, what's the timeline of the proposed first contract re development, etc.?

thanks

-----Original Message-----

**From:** Carchman, Loreen  
**Sent:** Wednesday, August 01, 2001 8:49 AM  
**To:** Osborne, Kevin (PMMC Legal); Venable, Bristow  
**Cc:** Oey, Jan  
**Subject:** FW: Contract Language for Main TES

Kevin,

Here is the proposed timeline for the TES study.

-L

-----Original Message-----

**From:** Jill Schultz [SMTP:jill.schultz@Covance.Com]  
**Sent:** Sunday, July 08, 2001 9:45 PM  
**To:** Loreen.L.Carchman@pmusa.com  
**Cc:** Jan.Oey@pmusa.com; Roger.A.Walk@pmusa.com  
**Subject:** Contract Language for Main TES

Dear Loreen,

Attached is an example of a Phase II-III contract and an Investigator Agreement for reference in preparing the draft contract for the main TES. We would suggest that two contracts be prepared, one for study design/feasibility and one for the actual study. The first contract could be prepared and signed rather quickly I would think.

The following draft timeline was provided in my minutes of Jan's visit to Covance on 05/10/01:

End of 11/01 Power analysis completed to determine no. of subjects, visits, biomarkers, etc.  
End of 11/01 Begin site selection  
03/01/02 Protocol milestones finalized  
04/15/02 Draft protocol to PM for review (2-week turn around on review)  
05/15/02 Final protocol  
06/16/02 Contract signed (PM and subcontract with individual sites)  
06/15/02 Investigator Meeting  
07/15/02 Lead site to start enrollment  
09/15/02 Remaining sites to complete start of enrollment

Please let me know if you would like me to set up a conference call to discuss further.

Best regards,

Jill

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